

**REMARKS**

The insertion into claims 16 and 31 of the use of a protein complex “for a sustained release of a preparation drug” is supported, for example, on page 4, lines 20-23 of the specification, and the insertion into the same claims of the Markush group of four proteins and pure epigallocatechin gallate as the polyphenol is supported on page 3, lines 1-3 and Examples 1, 2, 3 and 6 of the specification.

Reconsideration of this application, as amended, is respectfully requested.

Claims 16, 29-31, and 35-37 remain in the application.

Claims, 31, 35 and 36 have been provisionally rejected under the judicially created doctrine of double patenting over claim 5 of copending Application No. 09/571,960, Pub. No.: US 2002/0164795 A1 (the '960 application). It is believed that this rejection will be overcome by a terminal disclaimer which applicant intends to file shortly and which will provide that any patent issuing from this application shall expire at a date no later than the expiration date of any patent issuing from the '960 application.

Claims 16, 31 and 35 have been rejected under 35 U.S.C. as being anticipated by Chai Salon, "evidenced by" Yang et al. Nemours Foundation and National Cancer Institute, all of which were obtained from the internet. In connection with this rejection, the Office Action states in the last two lines of the first paragraph on page 4 that Yang et al., National Cancer Institute, and Nemours Foundation are part of the Chai Salon reference, apparently because the latter references follow Chai Salon on the internet. However, there is nothing to support this conclusion and it appears obvious from their content that the references are entirely separate from each other.

It is also noted that Nemours Foundation does not appear to be a proper prior art reference since its copyright notice is dated 1995-2005 which does not establish that it was available to the public on or before February 27, 2002, the filing date of the present application, and that National Cancer Institute is apparently also not a proper prior art reference since it contains no evidence, such as a copyright notice, of when it was available to the public.

Proceeding now to the references cited in this rejection which do appear to have a publication date prior to the filing date of this application, Chai Salon discloses the preparation of tea by adding tea leaves to boiling water which

presumably extractst he polyphenols as well as other components of the tea leaves, and adding the tea to heated milk which is known to contain the common animal proteins casein, and albumin, while Yang et al. discloses that tea polyphenols have a high complexation affinity to proteins without mentioning any specific proteins. However, neither of these references discloses any of the four specific proteins in the Markush group of proteins, or the use of pure epigallocatechin gallate as the polyphenol, to which all the rejected claims are now limited. In connection with the use of pure epigallocatechin gallate as the polyphenol, it should be noted that there is no indication that the teas disclosed by Chai Salon contain any epigallocatechin gallate at all, and that Yang et al. teaches that commercial green teas contain several different polyphenols including epigallocatechin gallate, with no indication that the latter compound should be used in its pure form. It is submitted, therefore, that the rejection of these claims, as anticipated is now inapplicable in view of the foregoing amendment and should be withdrawn.

Claims 16, 30, 31 and 35 have been rejected as being anticipated by Lehmberg eta l., U.S. Patent 5,952,023 which discloses a process for the preparation of instant tea including the extraction of black tea leaf with water containing tannase and one or more cell wall digesting enzymes. It is believed that this rejection has been overcome by the amendment of claims 16 and 31 to limit the

protein to any of a Markush group of four proteins, none of which is included in the group of digesting enzymes disclosed in Lehmberg et al., and to limit the polyphenol to a single polyphenol, namely, pure epigallocatechin gallate in contrast with the multiplicity of polyphenolic type biopolymers such as theaflavins and thearubigens present in black tea leaf as disclosed in Lehmberg et al.

Claims 16, 29, 31 and 36 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. and Chai Salon. It is submitted that this rejection is not well taken, particularly in view of the foregoing amendment. Note that there is no disclosure or suggestion in the references which would lead a person having ordinary skill in the art to form a protein complex by combining one of the four proteins of the Markush group now recited in claims 16 and 31 with pure epigallocatechin gallate as the polyphenol, to which amended claims 16 and 13 are also now limited. Note also that the teas of the references contain several different species of polyphenols and there is nothing in the disclosures of the references which would cause a person skilled in the art to alter such disclosures by limiting the polyphenols to a single one, namely, pure epigallocatechin gallate. This conclusion is strengthened by the fact the invention claimed herein and the subject matter of the references are applicable in entirely different technical fields, with this application claiming a protein complex useful in the preparation of a

sustained release drug while the disclosures of the references describe dietary products prepared from tea and milk (Chais Salon) or the composition of teas intended as a beverage (Yang et al.).

The unobviouness of the claimed invention under 35 U.S.C. 103(a) is also bolstered by an unexpected result not suggested in the references but critically significant when obtained from the use of the protein complex claimed herein which is intended for a sustained release drug, namely the property of slowly eluting protein molecules from the protein complex, as shown in Examples 1, 2, 3 and 6.

Finally, the patentability of new claim 37 reciting a protein complex “consisting esentially” of the protein and polyphenol of claim 31 is believed to be particularly strong since any protein complex formed by following the teachings of Chai Salon or Yang et al. Is likely to include significant components other than the protein and polyphenol, which components are excluded by the phrase “consisting essentially of” in applicant’s claim 37. In support of this conclusion is the fact that the composition of Chai Salon and Yang et al. contain various significant components other than proteins and polyphenol, which affect the properties of these compositions, such as the alkaloids in the tea leaves of both references and the

water, sugars (e.g. lactose in milk) and spices in the dietary preparations of Chai Salon. In this connection, it is noted that Yang et al. teaches that tea polyphenols have complexation affinity to metals, alkaloids and biologic macromolecules other than proteins, including lipids, carbohydrates and nucleic acids.

This application is now thought to be in condition for allowance, and such action at an early date is earnestly solicited.

Applicant respectfully requests a first one-month extension of time from July 25, 2005 to August 25, 2005. Please charge the fee of \$120.00 for the first one-month extension to Deposit Account No. 10-1250.

Respectfully submitted,

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